IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

SYNGENTA SEEDS, INC.,)
Plaintiff,)
V.) Civ. No. 02-1331-SLR
MONSANTO COMPANY, DEKALB GENETICS CORP., PIONEER HI-))
BRED INTERNATIONAL, INC.,)
DOW AGROSCIENCES, LLC, and MYCOGEN PLANT SCIENCE, INC.)
and AGRIGENETICS, INC.,)
collectively d.b.a. MYCOGEN)
SEEDS,)
)
Defendants.)

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MEMORANDUM OPINION

Dated: November 19, 2004 Wilmington, Delaware

ROBINSON, Chief Judge

I. INTRODUCTION

Plaintiff brought the present action on July 25,

2002, alleging infringement of, inter alia, U.S. Patent No.

6,320,100 ("the '100 patent"). Currently before the court (among dozens of other motions) is plaintiff's motion for summary judgment that claim 26 of the '100 patent is infringed and not invalid. (D.I. 274) For the reasons set forth below, the court denies plaintiff's motion with respect to infringement but grants the motion with respect to validity. Plaintiff asserts that two of defendants' products, MON810 and TC6275, infringe claim 26 of the '100 patent. (D.I. 275 at 1) Claim 26 depends from claims 18, 21, 23, 24, and 25, which claims have been construed by the court in its memorandum order dated November 19, 2004. (D.I.)

II. STANDARD OF REVIEW

A court shall grant summary judgment only if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The moving party bears the burden of proving that no genuine issue of material fact exists. See Matsushita Elec.

Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 n.10 (1986).
"Facts that could alter the outcome are 'material,' and disputes

are 'qenuine' if evidence exists from which a rational person could conclude that the position of the person with the burden of proof on the disputed issue is correct." Horowitz v. Fed. Kemper <u>Life Assurance Co.</u>, 57 F.3d 300, 302 n.1 (3d Cir. 1995) (internal citations omitted). If the moving party has demonstrated an absence of material fact, the nonmoving party then "must come forward with 'specific facts showing that there is a genuine issue for trial." Matsushita, 475 U.S. at 587 (quoting Fed. R. Civ. P. 56(e)). The court will "view the underlying facts and all reasonable inferences therefrom in the light most favorable to the party opposing the motion." Pa. Coal Ass'n v. Babbitt, 63 F.3d 231, 236 (3d Cir. 1995). The mere existence of some evidence in support of the nonmoving party, however, will not be sufficient for denial of a motion for summary judgment; there must be enough evidence to enable a jury reasonably to find for the nonmoving party on that issue. See Anderson v. Liberty <u>Lobby</u>, <u>Inc.</u>, 477 U.S. 242, 249 (1986). If the nonmoving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. See Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986).

III. INFRINGEMENT

A. Legal Standard.

A determination of infringement requires a two-step analysis. First, the court must construe the asserted claims so as to ascertain their meaning and scope. Second, the claims as construed are compared to the accused product. See KCJ Corp. v. Kinetic Concepts, Inc., 223 F.3d 1351, 1355 (Fed. Cir. 2000). Claim construction is a question of law while infringement is a question of fact. See id. To establish literal infringement, "every limitation set forth in a claim must be found in an accused product, exactly." Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1575 (Fed. Cir. 1995). Occasionally, "the issue of literal infringement may be resolved with the step of claim construction, for upon correct claim construction, it may be apparent whether the accused device is within the claims." Multiform Desiccants, Inc. v. Medzam, 133 F.3d 1473, 1476 (Fed. Cir. 1998).

B. Analysis.

There is a genuine issue of material fact as to whether defendants infringe claim 26 of the '100 patent. In order to infringe dependent claim 26 of the '100 patent, defendants must make, use, sell, or offer to sell a product which contains all of the limitations of claims 18, 21, 23, 24, 25 and 26. See 35

U.S.C. § 271 (2004); Exxon Chem. Patents, Inc. v. Lubrizol Corp., 64 F.3d 1553, 1559 (Fed. Cir. 1995). As a result, defendants' products must include: (1) transgenic seed (claim 26); (2) from

a transgenic maize plant (claim 25) comprising; (3) transgenic plant cells (claim 24) containing; (4) a chimeric gene (claim 23) having a heterologous promoter and synthetic Bt gene (claim 21); (5) which synthetic Bt gene was modified to increase expression in corn and encodes a Bt protein; and (7) contains a sufficient number of the claim preferred codons such that the G+C content of the synthetic DNA is at least about 60% (claim 18). (D.I. 275 at 22)

MON810 and TC6275 produce seeds that contain genetic material from other organisms. (D.I. 276 at A0004-A0006, A0023) MON810 and TC6275, therefore, produce transgenic seeds as required by claim 26. MON810 and TC6275 are also corn plants that contain genetic material from another organism, making each a transgenic maize plant according to claim 25. (Id. at A0006, A0020, A0074, A0128) MON810 and TC6275 are made up of plant cells that contain genetic material from other organisms, meaning each is comprised of transgenic plant cells as required by claim 24. (Id. at A0020, A0128, A0162-A0163) MON810 also contains a chimeric gene comprising a Bt gene linked to a heterologous promoter, the enhanced 35S promoter derived from cauliflower mosaic virus as required by claims 23 and 21. (Id. at A0012-

The court does not consider whether defendants' products possess the process limitations in claim 26, consistent with its discussion in its claim construction analysis and <u>Scripps Clinic & Research Found. v. Genentech</u>, Inc., 927 F.2d 1565, 1583 (Fed. Cir. 1991).

A0013, A0130) Similarly, TC6275 contains the Zea mays ubiquitin 1 promoter which is a heterologous promoter sequence operatively linked to the Bt coding sequence to promote expression of the CryIF protein as required by claims 23 and 21. (Id. at A0027)

MON810 and TC6275 both comprise a synthetic DNA coding sequence that encodes a Bt insecticidal protein selected for optimized expression in a plant as required by claim 18. (Id. at A0008, A0057-A0058, A0075-A0076, A0162) However, claim 18 also requires that the synthetic DNA coding sequence contain a sufficient number of the listed codons to raise the G+C content to 60%. Defendants used different lists of codons to construct the MON810 and TC6275 synthetic DNA coding sequences. For MON810, this list identified TCC, not AGC, as the preferred codon for the amino acid Serine ("Ser") and identified GTC, not GTG, as the preferred codon for the amino acid Valine ("Val"). (D.I. 338 at 4) Defendants used a third list of preferred codons to construct TC6275. This list identified different codons for the amino acids Leucine ("Leu") and Proline ("Pro"). (Id. at 5) Consequently, the codons used by defendants for Ser and Val in MON810 and for Leu and Pro in TC6275 cannot contribute "G"s or "C"s to the G+C content calculation under claim 18. Plaintiff has produced no evidence to show that, even excluding the Ser and Val "G"s and "C"s in MON810 and the Leu and Pro "G"s and "C"s in TC6275, defendants still have a DNA coding sequence that has a

G+C content of 60% under plaintiff's formula. Consequently, plaintiff has not shown an absence of a genuine issue of infringement by defendants.

IV. VALIDITY

A. Prior Invention.

Prior inventions must exhibit all the limitations of the claimed invention. Slip Track Sys., Inc. v. Metal-Lite, Inc., 304 F.3d 1256, 1265-66 (Fed. Cir. 2002). One of the limitations of claim 26 is that the claimed DNA coding sequence must have a G+C content of 60%. Defendants have conceded that neither Bt11 nor the prior Monsanto work had a G+C content of 60%. (D.I. 338 at 15, 19) The evidence produced in this case supports the conclusion that Bt11 and the prior work of Monsanto did not have a G+C content of 60%. (D.I. 276 at A0446, A0152) As a result, neither Bt11 nor the Monsanto's work are prior inventions of claim 26.

B. Anticipation.

"A rejection for anticipation under Section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference." In re Paulsen, 30 F.3d 1475, 1478-79 (Fed. Cir. 1994); see also Crown Operations Int'l, Ltd. v. Solutia, Inc., 289 F.3d 1367, 1375 (Fed. Cir. 2002) ("A patent is invalid for anticipation when the same device or method, having all of the elements contained in the claim

limitations, is described in a single prior art reference.")
Claim 26 of the '100 patent contains the limitation that the
claimed DNA coding sequence must have a G+C content of 60%. None
of the prior art references cited by defendants contain 60% G+C.
The Bt11 gene had a G+C content of 49%. (D.I. 276 at A0446) The
plants from Monsanto's experiment on GUN147 had a G+C content of
49%. (D.I. 275 at 26) The Barnason abstract and the Armstrong
EUCARPIA abstract, both of which relate to the GUN147 plants, not
only did not mention a G+C content, but also did not enable one
skilled in the art to practice the invention. (D.I. 277 at
A0496-A0499, A0668-A0670) Similarly, Monsanto's GUN284 and
GUN295 plants did not have a gene with more than 50% G+C content.
(Id. at A0471-A0472)

Finally, the Lundquist patent, U.S. Patent No. 6,331,665 ("the '665 patent"), does not provide any specific target for G+C content. The '665 patent specification states that "[t]he complete Bt coding sequence, or sections thereof, containing a higher proportion of maize preferred codons than the original bacterial gene could be synthesized using standard chemical synthesis protocols." Defendants point to this language as evidence that the '665 patent allowed one of skill in the art to use the '665 patent to make the seeds of claim 26. However, this statement does not suggest that one of skill in the art should modify a DNA sequence to have a G+C content of 60%. It only

states that such a DNA sequence could be made. In any event, the language cited by defendants certainly does not teach one of skill in the art to make a gene sequence containing 60% G+C.

C. Obviousness.

A patent claim is invalid for obviousness under 35 U.S.C. § 103 if the differences between it and the prior art are such that the claimed subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the invention was Union Carbide Plastics & Tech. Corp. v. Shell Oil Co., 308 F.3d 1167, 1187 (Fed. Cir. 2002). "Obviousness is a legal conclusion based on . . . : (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations, if any, of nonobviousness." McNeill-PPC, Inc. v. L. Perrigo Co., 337 F.3d 1362, 1368 (Fed. Cir. 2003). When the party alleging obviousness fails to demonstrate the existence of a motivation to combine references, the obviousness defense fails and summary judgment is appropriate. Kolmes v. World Fibers Corp., 107 F.3d 1534, 1541 (Fed. Cir. 1997). However, "the motivation to combine may be found 'in the knowledge generally available to one of ordinary skill in the art.'" Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., <u>Ltd.</u>, 357 F.3d 1319, 1337 (Fed. Cir. 2004) (<u>citing In re Jones</u>, 958 F.2d 347, 351 (Fed. Cir. 1992)).

Defendants have not produced sufficient evidence to create a genuine issue of material fact as to the obviousness of claim 26. First, defendants did not identify any prior art that suggests modifying a DNA coding sequence so that it contains 60% G+C content. Neither of the Fowler Australian Patent Office documents, AU-B-46881/89 and AU-B-36568/89, describes a Bt insecticidal protein modified to have 60% G+C content. (D.I. 277 at 500) If anything, the Fowler publications teach away from a DNA coding sequence containing 60% G+C since they teach that synthetic genes can only be synthesized by the methods described when the gene encodes small proteins of less "than 150 [100] amino acids." (D.I. 276 at A0508-A0510) U.S. Patent Application No. 01/0003849 ("the Barton application) also did not teach a DNA sequence with 60% G+C. The Barton application describes results from three different modified Bt genes, Bt2, Bt3, and Bt4. Bt4, the gene that had the most modification, only had a G+C content of about 43%. (D.I. 277 at A0700-A0713; D.I. 275 at 29) Furthermore, Barton actually teaches away from a DNA coding sequence of 60% G+C since it shows that the modified Bt genes with less modification were more effective at killing insects. (D.I. 277 at A0712; A0504-A0506) Thus, Barton does not teach modification of a DNA coding sequence to have 60% G+C. The Adang patent, U.S. Patent No. 5,380,831, also does not describe a DNA coding sequence with 60% G+C. Adang teaches that the G+C content should be adjusted preferably to 40% and most preferably to 45%. (D.I. 277 at A0962) Finally, the Fischhoff patent, U.S. Patent No. 5,500,365, does not include a DNA sequence with 60% G+C. None of the genes provided as examples in the Fischhoff patent have a G+C content greater than 50%. (D.I. 277 A0633, A0635-A0639)

Second, even if defendants had identified prior art containing all the limitations of claim 26, they failed to identify any motivation to combine the references cited. Defendants' opposition does not identify any reference that suggests combining any of the prior art cited in the opposition. Defendants, therefore, failed to identify an express written motivation to combine references. Defendants also failed to identify a motivation to combine references based on the knowledge generally available to one of ordinary skill in the art. Defendants argue that several of the limitations in claim 26 were well known in the art at the time of plaintiff's invention. (D.I. 338 at 25-28) While this may have been true, the fact that the limitations were well known does not suggest that it was obvious to combine these well known limitations of claim 26. Consequently, defendants failed to identify a motivation to combine the references.

D. Written Description.

Defendants also fail to identify a material issue regarding the sufficiency of the written description supporting claim 26. Defendants argue that the '100 patent specification does not support construing claim 26 to cover all DNA coding sequences with at least about 60% G+C. According to defendants, the '100 patent specification only describes optimized DNA sequences in which all of the native codons have been replaced by codons most preferred by maize except for minor variations to permit manipulation of the gene or to eliminate potentially deleterious processing sites. (D.I. 338 at 36) This, however, is not true. The '100 specification generally describes "[a]n optimized gene or DNA sequence" as one in which "the nucleotide sequence of a native gene has been modified in order to utilize preferred codons for maize." ('100 patent, col. 8, 11. 51-53) specification goes on to differentiate between a "pure maize optimized gene", wherein the "nucleotide sequence comprises 100 percent of the maize preferred codon sequences for a particular polypeptide," and "partially maize optimized" DNA coding sequences that contain at least about 5% optimized sequences." ('100 patent, col. 8, 11. 57-60; col. 9, 11. 5-15) As a result, the '100 specification does describe maize optimized DNA coding sequences with significantly less than all native codons replaced by maize preferred codons.

IV. CONCLUSION

For the reasons set forth above, the court denies plaintiff's motion with respect to infringement but grants the motion with respect to validity. An order shall issue.